White Paper
Image-Guided Interventions: Federal Inter-Agency Retreat

REPORT FROM THE IMAGE-GUIDED INTERVENTIONS FEDERAL AGENCY RETREAT
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The Interagency Image-Guided Interventions (IGI) Group, a trans-agency Special Interest Group (IGI Group, http://www.nih.gov/sigs/igi/.), held its first Federal Agency Retreat on Image-Guided Interventions on January 24, 2006 at the Lister Hill Auditorium located on the NIH campus. The overall mission of the IGI Group is to coordinate efforts among federal agencies, to leverage resources, and to plan future initiatives in research and development of image-guided interventions. The specific goals of the January 24th retreat were to identify important Grand Challenges (GC) for IGI and the resources and course of action across the federal agencies needed to implement them. The IGI Group's retreat planning committee spent months in getting the objectives, discussion topics, and potential action items prepared and organized.

The retreat brought together program staff of federal government agencies interested in advancing IGI technologies that span several agency missions. Participants represented a wide range of Federal Agencies including CMS, DOD, DOE, FDA, NASA, NSF, NIST and several institutes from the NIH including NIBIB, NHLBI, CSR, CC, NLM, NCI, NHGRI, NIAMS, NIGMS, NICHD, NINDS, NIDDK and NCRR.

The overall goal of the Special Interest Group is to plan future initiatives in image-guided interventions. The specific goals of the January 24th retreat were to identify important Grand Challenges for IGI and the resources and course of action across the federal agencies needed to implement them.

The retreat was conducted in a series of breakout group meetings and large group discussions throughout the day. Three breakout groups reported back to the larger group

on the importance of specific Grand Challenges and potential courses of action that might be implemented. A summary of the discussions is provided below.

Summary of breakout group discussions

- **Combine the short and long term Challenges**
- **Consensus on validation, standards, and integration of multidimensional data as high priority areas**
- **Relevance to agency missions**
- **Addition of a tenth Grand Challenge**

Consistent across the three groups was the idea that most, if not all, of the Grand Challenges could be defined as both short-term and long-term initiatives. While there is an immediate need for advances in technologies and processes such as validation and standards development, those fields will need constant updating with the advent of new technologies and complexities. Thus, the distinction between short and long-term challenges was eliminated when describing what might be accomplished in relation to specific Grand Challenges.

Two of the breakout groups reached consensus on the two highest priority areas:-(1) technical and clinical validation; standards; and (2) real-time integration of multidimensional images and other data for IGI. The third group indicated that all the predefined nine Grand Challenges discussed were components of a larger Grand Challenge: the advancement of IGI.

Agency-specific areas of interest were noted, as well as the recognition that all agencies will likely benefit from advances in each Grand Challenge. For a particular Challenge, an agency for which that Challenge is highly relevant is likely to take a leadership role, with other agencies providing consulting support.

A tenth Grand Challenge was suggested by one group. This Challenge is the need for long term outcome data which tracks both positive and negative impacts, in terms of public health and economic impact, resulting from technology or process advances in IGI. The descriptions of some of the other nine Grand Challenges were also edited by the groups.

Grand Challenge: Multidimensional Data Integration, Visualization and Feedback for IGI

All three breakout groups independently suggested that the Challenge that was originally titled, "4-D Visualization, Data Integration And Feedback" be renamed to reflect integration of higher-dimensionality data, such as 5D or even higher. This data may include multidimensional and multimodal images (e.g., real-time 3D images), as well as other data related to the intervention (e.g., physiological information, orientation information, symbols, text and time as ~~a~~ factors). Advancing technologies enable real-time 3D-image acquisition to guide treatment with ultrasound, MRI, CT, optical imaging, etc. Such real-time acquisition can capture and provide to the interventionalist

information about the patient's physiological status, detailed anatomy, and tissue/organ deformation. The Challenge of multidimensional data integration is largely software driven (other than the need for fast image acquisition devices) and is expected to be relatively low cost to implement. Software, modeling/simulation, and 4D imaging are areas of common interest to all agencies.

Grand Challenge: Standards for IGI

The meeting discussion on standards for IGI was expanded to include not only informatics standards, but also standards for IGI imaging and interventional devices. Development of standards for IGI could facilitate the integration of imaging and data systems. In addition, standards could be established for data acquisition, storage, communication, and software and thereby improve the interoperability of systems. Together IGI informatics and standards will make possible the seamless integration and fusion of heterogeneous multimodality imaging information and the interoperability of image-guided intervention tools, and yield true plug-and-play capability. Advances in informatics have the potential to vastly improve IGI by allowing for image-based queries of large scale IGI databases, integration of multimodal image information, communication of IGI data between different clinical sites, and compression of data via image interpretation techniques**.** Some agencies (e.g., NIST) have activities to develop standards as their mandate, but standards play a role in the missions of all agencies as they contribute to the productivity and potential of the entire scientific and technical community.

Grand Challenge: IGI Validation

A critical step in the final acceptance of any new image-guided intervention is validation. Validation data are needed for all new image-guided intervention developments, from the most basic new algorithms to new clinical treatments. Criteria for appropriate validation of techniques and technology are found in all aspects of IGI, including creation of databases against which to compare results, gold standards for assessments of accuracy, and clinical data requirements to demonstrate the safety and effectiveness of new image-guided interventions. Improvements in validation methods promise to decrease the time lag between development of technologies and their integration into the clinical arena.

Implementation

An observation was made in group discussion that there are challenges to implementation, whether it is a research or technology advance, validation initiative, or change in standards. To be effective, change needs to be embraced as an improvement over the status quo: by the professional medical community, patient population, and other stakeholders. There is a cost/benefit assessment to determine how the cost of new technology, validation of new research or technology, or change in standards compares to the perceived benefits derived from the change. There is also the challenge of reaching widely ranging communities with differing levels of resources to draw from. These and other factors may create a time lag between development or validation, and widespread implementation.

In addition to the three Grand Challenges listed above, seven additional topics were discussed:

- Special populations
- Training for IGI
- Combination of screening, diagnosis and treatment
- Semi-autonomous and image-guided robots
- Combination therapies/devices; externally activated therapies
- Novel signals for IGI
- Long-term outcomes data

Summary of the Action Items Discussed at the IGI Retreat

- NIBIB indicated that they will release in 2006 an initiative for IGI funding in FY07.
- NSF expressed an interest in exploring an interagency solicitation, for which the multi-scale modeling solicitation may serve as a model.
- The possibility of 3-5 new IGI Centers was also discussed. It was noted that in planning for one new center, one should think about 30-40 million dollars over 10 years.
- Participants suggested that ~~explore~~ other forms of inter-agency collaboration be explored. These include in-kind collaboration, SBIR programs, consortium networks, and investigator networks. There was particular interest in the creation of an IGI framework to network existing IGI Centers supported by multiple agencies such as:
    - Biophotonics, Subsurface Imaging, and Computer Assisted Surgery supported by NSF
    - Field Centers, Research Partnership Centers, and the National Space Biomedical Research Institute supported by NASA
    - Image-Guided Therapy center supported by NIBIB
    - NIST labs funded by NIST
    - HIFU center supported by NASA and NCI
    - Congressional special interest programs in IGI supported by DOD
- Fostering partnerships between academic research groups and private companies and professional societies.
- An Interagency Consortium for IGI (IC-IGI) was suggested by one participant. Such a consortium would advise applicants about government funding for clinical research, regulatory approval and Medicare (CMS) support of new IGI technologies.

Path forward for the Interagency Image-Guided Interventions (IGI) Group

- Summarize report and distribute to workshop participants.
- Use the existing interagency team to take findings from workshop and develop specific actions
    - Use existing programs and resources for balance of FY 2006 and FY 2007
    - Link to already planned initiatives and solicitations identified at the IGI workshop.
    - Examine areas of high priority identified in the workshop that are within each participating agency's mandate and that would be advanced through interagency partnerships, as part of planning for FY 2008 efforts that may require new monies.

IMAGE GUIDED INTERVENTION
RED AND GREEN AND BLUE TEAM DISCUSSION OF THE GRAND CHALLENGES

During the breakout discussion which lead to the group findings noted in the report summary, a number of comments and reflections were offered by breakout group members in the brainstorming sessions. The sections below capture the free-flowing ideas raised during the discussions that helped lead to the conclusions drawn, but also offer useful insight as individual comments. Following each grand challenge description is the range of breakout session comments captured in bullet form without prioritization or intent to formally integrate the individual comments.

GRAND CHALLENGE 1: 4-D VISUALIZATION, DATA INTEGRATION AND FEEDBACK

"Interventions in the future will be guided by information that includes images, symbols, text, and other knowledge including feedback to the operator or interventionalist. Currently, pre-operative images are often used to plan and guide treatment. The time interval between image acquisition and treatment procedure ranges from an hour to days. However, advancing information technologies enables 3D-image acquisition of real-time images to guide treatment with ultrasound, MRI, CT, optical imaging, etc. Technological advances would include acquisition and real-time use of 3D-images while tissue changes (deforms) during a procedure. In addition, information about a patient's physiological status, detailed anatomy, etc. and feedback about the procedure could be provided during image-guided interventions."

- This Grand Challenge was seen to have short term aspects with the ability to respond in real-time now with current software capabilities (virtual angiography system is personalized to a patient's requirements) and computing technology currently available for imaging, but the overall development timeframe was seen as a continuum with short and long-term development aspects.
    - Technologies are always evolving both in computing speed and new modalities.

- The Red Team recommended changing this Grand-Challenge from 4-D to a 5th Dimension or multi-dimension, to reflect energy and contrast dose. Time was also discussed as another dimension to address in imaging and treatment.

- The Green Team recommended revising the title of this GC to read ”Develop the technologies for integration of multimodal data and a closed feedback loop during IGI.”

- The Green Team recommended changing this Grand-Challenge from ‘multi-modal,’ or ‘multi-dimensional.’

- The Green Team also recommended revising the last sentence above to suggest ‘closing the feedback loop,’ i.e., “In addition, information about a patient’s physiological status, detailed anatomy, and information about the intervention should be provided as part of a closed-loop system during IGI.”

- Research timeframe differs from clinical implementation timeframe; implementation may take much longer than the research or technology advance itself.

- There are limitations to success: in total joint replacements, frequency of surgical performance affects success of the outcome; this challenge translates to a number of aspects in IGI technologies.

- On-line feedback intervention systems can compensate for movement during radiation treatment; imaging can be used to provide correct dosage to target area and minimize the amount of dosage impacting non-target areas.

- The real-time aspect of imaging technology is important; errors present in initial assessment can propagate and compound; real-time imaging may reduce the risk of errors gaining momentum in their negative impact.

- There was a recurring discussion on diverse communities and subsequent variation in visualization, data integration and feedback technology capability
    - Central venous access availability to military medical personnel on the battlefield, but this capability is not widely available to all civilian populations
    - Clinical monopoly on highly-complex technology impacts the degree of utilization by stakeholders
    - User-friendliness of the technology needs to be considered as part of the challenge in implementation
    - The targeted use of technology can become a point of contention, as sub-specialties vie for dominant use/implementation. Registration imaging is an example of technologies with two different interest groups vying for different approaches.

- Cost becomes an important factor. High-tech, costly technologies may limit the beneficial outcome and scope of implementation. Therefore, cost-effective implementation is important.

- Relevance to agency mission becomes a factor in multi-dimensional visualization, data integration and feedback, though software, modeling/simulation and multi-dimension imaging are common to all research agencies.
    - If barriers can be removed between agencies to foster interaction, mutual needs can be more efficiently addressed.
    - An important outcome of this workshop will be to identify agency common needs which will also advance the individual agency mission
        - CDC/NICHD effort for trans-agency work is an example of recognized need to work across agencies.
- The blue team recommended that 4D should be specifically defined; call it N-D visualization with time, rotation, pressure, metabolism, etc as variables. For the rest of the grand challenges the blue group decided not to review each of the Grand Challenge separately, as had the other groups. However the blue group felt that "IGI" is the Grand Challenge.

GRAND CHALLENGE 2: NOVEL SIGNALS FOR IGI

"Novel signals from molecular imaging agents and other probes can be used to guide interventions. IGI technologies are rapidly evolving and can be designed to include functional, cellular and molecular imaging as well as other signals indicating physiological activity. For example, electrical activity in the heart can be mapped to guide the treatment of arrhythmias; signals from functional MRI and PET may be combined to better guide neurological surgery; optical imaging agents might be used to guide tumor resection; and PET images are guiding radiotherapy treatments in the lung, prostate and brain as well as their follow-up. Furthermore, nanocarriers may be developed to localize a disease site for targeted imaging and therapy of the disease."

- The Red Team noted that there are immediate needs which can be addressed in the short term, even if there are also long term research investments and development cycles.
- One short term goal would be the development of an optical probe with antibody and contrast agent, which may be the first application of a new IGI intervention development.
    - Probe development is highly interdisciplinary and complex, requiring considerable clinical feedback and communication.
    - Probe development is more complex than drug development; research risk from the standpoint of complexity is therefore high.

- More thorough evaluation is needed: PET imaging, FDG may be more attractive

- Molecular probes and imaging agents are developed independently of IGI, but there may be some commonalities.

- Enhanced probe technology development may be expensive but in the long term may reduce the number of tests required.

- Agency relevance remains a potential issue; agencies may benefit from the technology development but might not be in the forefront of said development if there is not a clear and strong link to a given agency's organization mandate.

GRAND CHALLENGE 3: VALIDATION

"A critical step in the final acceptance of any new imaging technology or image-guided intervention is validation, determination of whether an image-guided intervention is accurate and/or whether an image-guided intervention is safe and effective. Validation data are needed for all new developments in the field of image-guided intervention, from the most basic new algorithms to new clinical treatments. Acceptance of image-guided interventions by the medical community has been limited, despite years of intensive research. A major cause the limited acceptance and availability is the lack of validation data. The objective of this GC will be to establish criteria for appropriate validation of techniques and technology in all aspects of IGI, including development of acceptable databases against which to compare results, gold standards for final determination of accuracy of new image-guided interventions, and clinical data requirements to demonstrate the safety and effectiveness of new image-guided interventions."

- The Green Team recommended the development of a hierarchy of validation needs from proof of principle to full clinical trials; this GC focuses on clinical validation

- The Red Team again noted the continuum of technology development that all Grand Challenges, have, spanning short and long term goals and objectives.

- Validation helps to address ultimate usefulness of a particular technology. Validation is also important for reimbursement; IGI technologies may not be reimbursed if standards were not used.

- A comment was made that validation does not need to be an explicit Grand Challenge; integral to all technology development, it was not seen as an explicit and stand-alone initiative. Every approach needs validation before implementation, so what is the definition of validation being used here?

- There were several challenges identified regarding validation:
    - Clinical adoption of validation may be outpacing pre-clinical adoption of validation; it would be helpful to identify important pre-clinical targets for early validation to ensure clinical adoption.
    - There is also a challenge of technology or research acceptance outpacing validation; once an area of research or technology has been accepted in practice, it is difficult to undertake a comprehensive validation study that may raise questions about the research or technology in question.
    - Adopting validation standards across different applications will be very challenging.
    - There is a lack of availability of product assessment and validation tools
    - There is a lack of collaboration on sharing validation data and methodologies. Need improvement in such collaboration to shorten approval and acceptance timelines.
    - Standardized PET uptake values are not well characterized, even the definition of "white" is subject to debate.

- Agencies are intertwined regarding validation of research and technology:
    - NIST has a central role in validation but there is a connection with other agencies; NIST cannot conduct this work on its own, without other agencies voicing their support for this effort
    - CMS would like to see large-scale studies, but cannot conduct such studies alone and would like to work with other agencies
    - Task-specific performance (i.e. organ movement) validation activities are done across agencies. Other examples would be hypoxia measurement, 5D corrections "on the fly".

- Broad validation techniques applicable to broad classes of devices would be helpful.

GRAND CHALLENGE 4: IGI INFORMATICS AND STANDARDS

Together IGI informatics and standards will make possible the seamless integration and fusion of heterogeneous imaging information and the interoperability of image-guided intervention tools, yielding true plug-and-play capability. Advances in informatics have the potential to vastly improve IGI by allowing for image-based queries of large scale IGI databases, integration of multimodal image information, communication of IGI data between different clinical sites, and compression of data via image interpretation techniques. To fully benefit the IGI endeavor, informatics developments must be coupled with the adoption of standards

for IGI data acquisition, storage, and communication. Likewise, software standards and performance standards are necessary to guarantee the integration of component IGI technologies.

- There are aspects of this GC that can be addressed in under 5 years

- Problems of standardization not unique to IGI; need to work with others in imaging to address this, join forces
  - No need to create new standards where workable solutions already exist.
  - Adopt those that will work for IGI; focus development resources where greater gaps exist.

- Need for more content-based retrieval technologies.
- The team noted there are lots of extant data that need seamless exchange
- NIGMS, BECON, BISTIC, NCBC (Roadmap) focus on large validated databases and data exchange and are resources for all.
- DICOM format—Grand Challenge 4 is a lofty goal, but difficult to realize. The area having the most momentum is in commercial software. Open source is moving slowly. It may be difficult to engage the government in this rapidly expanding area of informatics and standards development.
  - Are there other IGI-specific needs of DICOM analogs? Imaging OEMs try to combine modalities and are having difficult time in software integration.
- Risk, in terms of complexity of the task, is substantial.
- Standards must be used to have an impact in technology development
- Some data collection at the time of study may not be applicable, but can be useful later.
- "Plug-and-play": different IGIs may use the same software platform to make systems interoperable.
- As for agency relevance, comparable to some of the other Grand Challenge, some agencies have standards activities as their mandate, but standards development benefits all agencies.

GRAND CHALLEGE 5: COMBINATION THERAPIES/DEVICES; EXTERNAL ACTIVATION

"Some therapeutic agents can be externally imaged, localized and activated. In these examples, therapeutic agents can be locally activated using external devices such as ultrasound devices that release therapeutic agents in a specified region of the body. Activatable imaging and therapeutic agents represent important opportunities for IGI. Selective activation by optical, acoustic, or other electromagnetic energy adds dimensions, in addition to biological and biochemical targeting, to combined imaging/therapy agents."

- In addition to biological and biochemical targeting, selective activation by optical, acoustic, or other electromagnetic energy allows immediate, direct therapeutic to (or application of) combined imaging/therapeutic agents."

- The Red Team noted once again that this area of technology development is part of a continuum rather than a sharp demarcation between short and long term.
    - There are near-term clinical trials now in external activation of therapeutic agents.

- Safety and efficacy remain challenges that add to the risk/complexity of this technology development, but will be very important factors to address.

- When combining modalities, it will be harder to define how to regulate or assess the effectiveness of this technology. Sequencing will be important in terms of the order of modalities applied.

- Questions must be asked in dealing with externally activated treatment therapies:
    - How many times can the technique be used?
    - Are there cumulative effects on the patient?

- In the course of group discussion, it was noted that this area of technology development will have wide application, from more effective treatment for a range of patients, to medical technologies to be used by astronauts as part of exploration missions. The area of telehealth presently has significant interest and benefit to space exploration and terrestrial medical care.
    - There was also a recognition that there are special populations that would benefit by externally activated therapy and minimized medical intervention:
        - elderly do not tolerate some medical interventions well, so this technology may help by minimizing the degree of surgical intervention
        - pediatric care can benefit by external activation on patients not fully developed

GRAND CHALLENGE 6: SEMI-AUTOMATED AND IMAGE-GUIDED ROBOTS

"Technology developments have produced advanced robotic devices and systems that yield accurate and minimally invasive surgeries. Robots are available today for hip replacement in orthopedic surgery, camera positioning for laparoscopic surgery, minimally invasive cardiac surgery, and needle placement for image-guided interventions. We must build on

the unique capabilities of surgical robots; precision, accuracy, strength, and dexterity. Technical advancements in robotic surgery must focus on improving imaging control and process planning. Finally, an important goal for advanced robotic systems is improving safety in the operating room."

- The Red Team noted that use of the word "surgeon" should be replaced with another term such as medical operator as image-guided robot operations could include many other applications apart from the surgical procedure itself, and therefore other skilled individuals besides surgeons may be participating in a procedure using the image-guided robot.

- Once again there was discussion about a continuum of technology development:
  - Robots used in medical procedures have been used for over a decade but the use remains limited due to safety concerns.
  - Telerobotics (i.e. DaVinci) still uses surgeon input; the reality is not complete robot autonomy.

- Robot technology in medicine is highly visible, both successes and failures. Acceptance by medical practitioners and the public may take longer than the timeframe for a particular robotic technology development. This different timeframe between technology development and longer timeframe for professional/public acceptance was noted in other Grand Challenge

- Image guided robotic surgery decreases the time for the surgical procedure, which benefits surgeons and patients alike.

- There will remain an important balance between robotic capabilities and human abilities to maintain skills, monitor and intervene when necessary:
  - Miniaturization of robots in medicine will enable procedures to take place that are not currently possible with human surgeons.
  - Molecular imaging techniques will render invisible images that robots may be better suited to address than a surgeon.
  - However, surgeons must maintain their capabilities and not allow their fine motor skills and other experience to atrophy. There must be ability for a surgeon to override the robotic procedures if there is a misinterpretation of information or technical anomaly such as sensor malfunction.

- As for societal impact, greater automation of medical procedures and surgical intervention have both positive and negative possibilities. As noted above, the human element must be maintained to mitigate any possible problems with automated procedures.

GRAND CHALLENGE 7: COMBINE SCREENING, DIAGNOSIS AND TREATMENT

"Combining diagnosis and treatment is critical for diseases where time-to-treatment is a crucial factor. The blurring of the distinction between imaging as a diagnostic tool and imaging for guiding treatment is a paradigm shift that could be facilitated by this grand challenge. The use of imaging technology is used as a minimally invasive or non-invasive means to monitor, diagnose and treat disease or injury. Imaging technology can be used for preventive care and early detection of disease or injury, as well as post-intervention monitoring of health indicators. IGI technology can also be used as an integral part of deployed telemedicine technologies that combine diagnosis and treatment in isolated communities or communities where natural disasters or conflicts have overwhelmed or established medical facilities."

- or in the military theater

- Once again, this technology development is along a continuum with near, mid and long term development objectives.
    - Optical imaging combined with ablative treatment in the same device as it treats cervical cancer is being developed now.
    - Combined diagnosis and treatment in radiography has been done for decades. However, is optical input sufficiently reliable to treat the patient? This may still take many years for the technology to reach maturity.

- NCI conducted a workshop on pre-cancer, non-invasive and non-traumatic treatments where there are less or no side-effects of the treatment.

- Microscopic pre-cancers may be highly prevalent and difficult to fully treat, i.e. thyroid cancer.

- Time-to-treatment is another important factor; reducing this time span is an important objective.

- There was a question regarding why this is being treated as a separate Grand Challenge.

- In the long term, genetic predictors may become part of the screening process. Screening may also help identify individuals at risk who could benefit from early preventative treatment.

- There was a discussion about removing the action of "screening" from the Grand Challenge objective, which is a CMS "red flag"…their organization is prevented from paying for screening tests. There was a concern about how screening could be manageable when the parameters may be quite wide.
    - The CMS representative recommendation was for IGI to focus on diagnosis and treatment without including general population screening.

    - This led to a general discussion on screening vs. focused imaging: Early detection through screening may save lives by combating disease early in its development. On the other hand, general screening is quite costly and may develop problems such as "false positives" as some screening approaches have very high sensitivity, not specificity. 3000 individuals could be seen to have nodules as part of a general screening process, but only a small fraction could have cancer; treatment for all of those identified with nodules would be very expensive.
        - The general observation was that screening may have merit, but should be carefully examined with benefits and drawbacks taken into consideration.

- The category of risk within the Grand Challenge of screening, diagnosis and treatment dealt with the need to safely balance diagnosis and intervention, including the need to minimize inaccurate findings that could lead to wrong intervention protocol.

- NCI is looking for nanotechnology to increase sensitivity and specificity of screening. Suspect nodules are treated non-invasively, an example of improved sensitivity and specificity in treatment.

GRAND CHALLENGE 8: TRAINING FOR IGI

Image-guided intervention training programs should incorporate imaging technology, interpretation, and intervention with understanding of disease mechanisms through the basic and clinical sciences. Training for image-guided intervention should be tripartite: (1) training in the basic sciences (e.g., molecular biology, pharmacology, and physics), (2) training in the clinical sciences with extensive training in radiology, and (3) training in intervention techniques integrated with (1) and (2) to produce technological proficiency initially by simulated intervention followed by patient intervention.

- As with other Grand Challenges, IGI training was noted as being part of a continuum. Evolving technology and capabilities will always result in the need for near term expertise with the technology, and will remain iterative in nature as new processes and technologies require further training to remain current with that technology.

- The Red Team noted that since IGI is multidisciplinary and multi-user, not just surgeons who will be obtaining and interpreting images, IGI training should reflect the professional diversity of individuals involved.

- In response to the question "is there currently a problem with adequacy of trained personnel, e.g. radiologists?" the answer was a clear "Yes".

- There is a greater need for scientists to provide quality assurance aspects for IGI. Bioengineering societies work on new modalities, but QA aspects are lacking. By contrast, in radiotherapies, there are many medical physicists focusing on QA.

- A concern was raised comparable to the issue of automated robotic technology vs. human intervention. Those individuals using IGI should understand the technology and algorithms being used. Can the imaging technology being used distort the information being sought? The IGI operator should be knowledgeable about potential errors, and know when to ignore/override the information being conveyed due to potential technical anomalies. There must also be the capability to address complications in the IGI procedure. As in Grand Challenge 6 with semi-automated and image-guided robots, there must always be an informed human in the loop to play an active, not passive role that may include challenging the IGI information being conveyed by the technology

- In the area of risk from the standpoint of complexity, those engaged in IGI should be better educated in addressing radiation exposure and protection countermeasures.

- Acceptance of IGI technologies depend greatly on training. Those professional who are comfortable with emerging and evolving technology may more readily accept new technologies.

- There are multi-dimensions to IGI beyond 3 or 4-D; a fifth dimension is radiation and other stimuli; energy deposition methods are non-linear, must be properly understood, and can also be exploited carefully. Others noted that time can be a dimension in medical procedures.

GRAND CHALLENGE 9: SPECIAL POPULATIONS

"Special populations are defined as patients whose characteristics require greater specialized IGI technologies than the general population. These can include infants, children, pregnant women, astronauts, the obese, elderly, disabled people, the critically ill, traumatically injured, the poor, uninsured, and those in developing countries."

- Another Grand Challenge that is a continuum linking near-term requirements and long-range challenges. Many near and long-term needs exist.

- Hurricane Katrina raised our awareness that special populations challenged by insufficient access to medical care and other essential requirements do not have to be Third World, but can be in our own cities. From birth to death, everyone will also be part of a "special population" at least part of their lifetime, some more than others.

- Development of new or improved IGI technologies must take into account physically vulnerable patients or other individuals that pose special challenges and constraints

- The needs of special populations can result in diverse IGI design requirements. For example, IGI capabilities associated with human space exploration must address miniaturization of hardware, optimization of power generation and minimalization of power consumption, volume and weight, all associated with physical space/mobility constraints.
    - Through such technology/medical advances, there will likely be broader space-faring populations than ever before.
    - Knowledge gained from the challenge of spaceflight has direct correlation to advances in terrestrial medical care.

- In terms of complexity as a risk factor, the diverse user populations found in the "special populations" Grand Challenge pose a challenge of how best to address the diverse needs and requirements.

- There was discussion on the difficult issue of meeting societal needs:
    - How is the requirement for complex or expensive technology that can meet the needs of a relatively small part of the patient population balanced against technology development and treatment that can benefit a larger segment of the population due to broader applicability? The question is similar to the challenge surrounding "orphan drugs" where the lives of a few may have to be balanced against the needs of a greater patient population who could benefit by more widely applicable treatments.

    - In a similar vein, all IGI is not applicable to all segments of the population. To the degree possible, IGI should be designed with applicability and/or adaptability to different patient/consumer populations, but at the same time bearing in mind the cost of doing so. The challenge, driven by fiscal constraints, comes down to selection when a technology cannot feasibly be all things to all people

The morning breakout session concluded with the Red Team selecting Grand Challenges 1 (4-D Visualization, Data Integration and Feedback), 2 (Novel Signals for IGI), and 4 (IGI Informatics and Standards) as the Grand Challenges most

addressing the criteria developed for the workshop, while recognizing the importance of the other Grand Challenges.

The Green Team suggested an additional GC:

GRAND CHALLENGE 10: LONG TERM OUTCOMES STUDIES

There is a need for data on long-term outcomes resulting from IGI. Epidemiological data need to be collected in general, as well as in special populations, to determine public health benefits and socioeconomic effects ~~aspects~~. There is also a need for data on adverse events or outcomes resulting from IGI.

The blue groups' agency representative responses
The blue group did not rank each grand challenge or discuss each grand challenge separately. Instead the blue group focused on the different agency missions and which grand challenges were important to that particular agency.

- NSF funds programs on subsurface imaging, image information/data integration for decision making, Grand Challenges 1,5,6,7 would be a good combination that would push technology forward and pull into the practical applications.
- The blue groups' NASA representative stated that NASA's mission is in the developing technology for astronauts, funding areas where the issues of space flight can be considered, to maintain research facilities with other institutes, by leveraging or collaborating, with super computers and data management, translation of technology, digital mammography. The NASA representative that that grand challenges 1-9 were of equal priority.
- The NIST representative in the blue group stated that NIST's work revolves around metrology, standards, and the safety of medical devices. The NIST representative thought the grand challenges 1, 2,3,4,6 were of highest priority.
- CMS's representative stated that CMS's mission is not concerned with the details of the technology functions, however CMS is more concerned with the technology being reasonable, necessary and the subsequent outcomes of the technology. CMS thought the grand challenges 3,7,8,9 were of most importance.
- The FDA's representative felt that the grand challenges 1,2,3,4,6 were the most important.
- NIH-NIBIB's representative thought that all 9 grand challenges were equally important.
- NIH-NHLBI's representative thought that all 9 grand challenges were equally important. NHLBI's mission is in cardiovascular areas and pediatrics.
- NIH-NCI's mission is outcomes metrics important, telemedicine, all GCs are vital. Population driven for end users clinical benefit. The bench to bedside pathway.
- CSR's blue group representatives thought that grand challenges 1-9 were of equal priority. CSR's mission lies in the areas of robotics, linking basic scientists to practical applications and funding issues.

AFTENOON SESSION
DISCUSSION

Individual Agency Reflections:

- NASA:
  - Validation and standards development are important, but not a NASA core priority in fulfillment of the agency's mandate and mission. Imaging technology as part of near or real-time treatment of astronauts ***is*** an important area that is also in line with the agency's exploration mission.

- NIST:
  - NIST's charter is to foster good measurements in all fields and to support a broad range of customers.
  - Though other agencies may not have standards and measurements as part of their respective charters it remains important for other agencies to voice development of effective standards and measurements as important areas to address. If the need for standards is not expressed as part of other agency needs, it becomes difficult for NIST to sustain support for these activities.

- CMS:
  - Validation is the "engineer driving the train".
  - CMS will help support clinical trials to show the clear efficacy of a medical procedure for Medicare beneficiaries, but only in a well-defined context.
  - CMS is prevented from conducting research, and ultimately works with research outputs sponsored by federal agencies.
  - CMS priorities align better with VA or AHRQ than some of the other federal agencies.

- FDA:
  - There is a critical path initiative to support development of tools that manufacturers can use to validate methods.

Red Team Determination of Priority:

- The Red Team recommended merging Grand Challenge 3, Validation, with a portion of Grand Challenge 4 to create the ***Grand Challenge "Validation and Standards"***
  - The team also recommended Informatics in *Grand Challenge 4* be moved to ***Grand Challenge 1, 4-D Visualization, Data Integration, Informatics and Feedback*** as being more appropriately placed there as informatics was deemed to be integral to data integration and feedback within Grand Challenge 1.

- As noted in the morning, session, Grand Challenge I and merged Grand Challenges 3,4 are not near or long term, but part of a continuum.

Next Steps:

- There was a question as to what could NIBIB support under Grand Challenges 3,4 that would complement the needs of other agencies. Validation infrastructure for a particular technology would be of interest to NIBIB within the focus of Grand *Challenge 1, Visualization, Data Integration, Informatics and Feedback.*

- There was a suggestion to propose review criteria or have a solicitation response requirement to include a validation component.

- There was a suggestion to use a "Request for Information" (RFI) to solicit comments and recommendations on how a future IGI contract could be developed that would be of interest to several agencies while directly supporting the goals and objectives of the sponsoring/funding agency.

- In response to the question "where will standards come from?" came suggestions including development of consensus and use of ISO/ASTM standards.

- Thoughts on improving interagency collaboration:
  - Interagency strategic road map
  - Leveraged partnerships: take advantage of NSF, NIH, NASA, and other agency research and technology centers by leveraging the resources, interests and capabilities of other agencies.
  - Interagency contract solicitations
  - CMS can be a driving force for near-term goals being addressed by the workshop participants.

- Identify specific linkage between individual Grand Challenges and respective agency need. Identify an agency representative to channel agency alignment with possible inter-agency collaboration on one or more of the 9 Grand Challenges.
  - There are often multiple solutions to a problem and collaboration can identify other perspectives, with resultant savings in time and money.

- Communication to foster collaboration and coordination is an ongoing need.

IGI Interagency Metrics

- Long-term success: if NIBIB-supported technologies will be successful as a direct result of interagency collaboration.
- Emergent technologies such as those supported by NIBIB lead to useable products
- The workshop helps bring about an interagency council on IGI facilitating progress from concept to market , by allowing technology developers to consult in parallel with funding, regulatory and reimbursement agencies.

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